

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Havenga et al.

Serial No.: 10/010,645

Filed: November 13, 2001

For: GENE DELIVERY VECTORS WITH
CELL TYPE SPECIFICITY FOR
MESENCHYMAL STEM CELLS

Confirmation No.: 4875

Examiner: B. Whiteman

Group Art Unit: 1645

Attorney Docket No.: 2578-5006.1US

NOTICE OF EXPRESS MAILING

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08A be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in

37 C.F.R. § 1.56(b). Further, no representation is made by Applicant herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
EP 1 020 529 A2	07/19/2000	Introgene B.V.
EP 1 067 888 A1	01/10/2001	Introgene B.V.
EP 1 279 738 A1	01/29/2003	Crucell Holland B.V.
WO 00/52186 A1	09/08/2000	Introgene B.V.

Other Documents

CONGET, P.A., et al., "Adenoviral-mediated gene transfer into ex vivo expanded human bone marrow mesenchymal progenitor cells," 28 EXPERIMENTAL HEMATOLOGY 382-390 (2000).

GOOSSENS, P.H., et al., "Infection Efficiency of Type 5 Adenoviral Vectors in Synovial Tissue Can Be Enhanced With a Type 16 Fiber," 44(3) ARTHRITIS & RHEUMATISM 570-577 (March 2001).

HAVENGA, M.J.E., et al., "Exploiting the Natural Diversity in Adenovirus Tropism for Therapy and Prevention of Disease," 76(9) JOURNAL OF VIROLOGY 4612-4620 (May 2002).

HAVENGA, M.J.E., et al., "Improved Adenovirus Vectors for Infection of Cardiovascular Tissue," 75(7) JOURNAL OF VIROLOGY 3335-3342 (Apr. 2001).

MARX, J.C., et al., "High-Efficiency Transduction and Long-Term Gene Expression with a Murine Stem Cell Retroviral Vector Encoding the Green Fluorescent Protein in Human Marrow Stromal Cells," 10 HUMAN GENE THERAPY 1163-1173 (May 1, 1999).

OLMSTED-DAVIS, E.A., et al., "Use of a Chimeric Adenovirus Vector Enhances BMP2 Production and Bone Formation," 13 HUMAN GENE THERAPY 133-1347 (July 20, 2002).

Other Documents

- ROELVINK, P.W., et al., "Identification of a Conserved Receptor-Binding Site on the Fiber Proteins of CAR-Recognizing Adenoviridae," 286 SCIENCE 1568-1571 (Nov. 1999).
- ROELVINK, P.W., et al., "The Coxsackievirus-Adenovirus Receptor Protein Can Function as a Cellular Attachment Protein for Adenovirus Serotypes from Subgroups A, C, D, E, and F," 72(10) JOURNAL OF VIROLOGY 7909-7915 (Oct. 1998).
- TURGEMAN, G., et al., "Bone Stem Cell Mediated Gene Therapy and Tissue Engineering," 15(7) JOURNAL OF BONE AND MINERAL RESEARCH S196 (Sept. 2000), Abstract.
- TURGEMAN, G., et al., "Engineered human mesenchymal stem cells: a novel platform for skeletal cell mediated gene therapy," 3 J. GENE MED. 240-251 (2001).
- VIGGESWARAPU, M., et al., "Adenoviral Delivery of LIM Mineralization Protein-1 Induces New-Bone Formation in Vitro and in Vivo," 83-A(3) THE JOURNAL OF BONE & JOINT SURGERY 364-376 (March 2001).
- YOTNDA, P., et al., "Efficient infection of primitive hematopoietic stem cells by modified adenovirus," 8(12) GENE THERAPY 930-937 (June 2001).
- Partial European Search Report, European Application No. 01202619, dated May 7, 2002 (4 pages).
- International Search Report, International Application No. PCT/NL02/00443, dated July 24, 2003 (6 pages).

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants hereby identify the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 2578-3833.5US
Serial No.: 09/918,029
Filing Date: July 30, 2001
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3833.6US
Serial No.: 10/038,271
Filing Date: October 23, 2001
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3833.7US
Serial No.: 10/125,751
Filing Date: April 18, 2002
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3833.8US
Serial No.: 10/219,414
Filing Date: 8/15/2002
Title: STOCKS OF REPLICATION DEFICIENT ADENOVIRUS

Attorney Docket No.: 2578-3833.9US
Serial No.: 10/618,526
Filing Date: July 11, 2003
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3840US
Serial No.: 09/065,752
Filing Date: April 24, 1998
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3840.1US
Serial No.: 09/900,062
Filing Date: July 6, 2001
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3840.2US
Serial No.: 10/396,548
Filing Date: March 25, 2003
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3935.1US
Serial No.: 09/912,552
Filing Date: July 23, 2001
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3955.1US
Serial No.: 10/136,139
Filing Date: May 1, 2002
Title: MEANS AND METHODS FOR NUCLEIC ACID DELIVERY
VEHICLE DESIGN AND NUCLEIC ACID TRANSFER

Attorney Docket No.: 2578-3982.2US
Serial No.: 09/517,898
Filing Date: March 3, 2000
Title: MEANS AND METHODS FOR FIBROBLAST-LIKE OR
MACROPHAGE-LIKE CELL TRANSDUCTION

Attorney Docket No.: 2578-4038.1US
Serial No.: 09/549,463
Filing Date: April 14, 2000
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Attorney Docket No.: 2578-4038.2US
Serial No.: 10/234,007
Filing Date: September 3, 2002
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Attorney Docket No.: 2578-4070.1US
Serial No.: 09/573,740
Filing Date: May 18, 2000
Title: SEROTYPES OF ADENOVIRUS AND USES THEREOF

Attorney Docket No.: 2578-4075US
Serial No.: 09/332,803
Filing Date: June 14, 1999
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-4080.1US
Serial No.: 10/235,175
Filing Date: September 4, 2002
Title: TARGETED DELIVERY THROUGH A CATIONIC AMINO ACID
TRANSPORTER

Attorney Docket No.: 2578-4123.1US
Serial No.: 09/953,280
Filing Date: September 14, 2001
Title: CHIMAERIC ADENOVIRUSES

Attorney Docket No.: 2578-4123.2US
Serial No.: 09/348,354
Filing Date: July 7, 1999
Title: CHIMAERIC ADENOVIRUSES

Attorney Docket No.: 2578-4192.1US
Serial No.: 09/657,492
Filing Date: September 8, 2000
Title: MODIFIED ADENOVIRAL VECTORS FOR USE IN GENE
THERAPY

Attorney Docket No.: 2578-4215.1US
Serial No.: 10/231,735
Filing Date: August 28, 2002
Title: INTERLEUKIN-3 GENE THERAPY FOR CANCER

Attorney Docket No.: 2578-4230US
Serial No.: 09/214,836
Filing Date: October 4, 1999
Title: MELANOMA ASSOCIATED PEPTIDE ANALOGUES AND
VACCINES AGAINST MELANOMA

Attorney Docket No.: 2578-4231US
Serial No.: 09/444,284
Filing Date: November 19, 1999
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE
TROPISM FOR SMOOTH MUSCLE CELLS, AND/OR
ENDOTHELIAL CELLS

Attorney Docket No.: 2578-4489US
Serial No.: 09/665,472
Filing Date: September 20, 2000
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR DENDRITIC CELLS

Attorney Docket No.: 2578-4489.1US
Serial No.: 10/646,449
Filing Date: August 22, 2003
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR DENDRITIC CELLS AND METHODS OF USE

Attorney Docket No.: 2578-4509.1US
Serial No.: 09/928,262
Filing Date: August 10, 2001
Title: GENE DELIVERY VECTORS WITH CELL TYPE SPECIFICITY FOR PRIMARY HUMAN CHONDROCYTES

Attorney Docket No.: 2578-4615.1US
Serial No.: 10/164,085
Filing Date: June 4, 2002
Title: COMPLEMENTING CELL LINES

Attorney Docket No.: 2578-4615.2US
Serial No.: 10/272,041
Filing Date: October 15, 2002
Title: COMPLEMENTING CELL LINES

Attorney Docket No.: 2578-4622.1US
Serial No.: 10/432,105
Filing Date: May 20, 2003
Title: ADENOVIRAL REPLICONS

Attorney Docket No.: 2578-4843US
Serial No.: 09/843,894
Filing Date: 4/27/2001
Title: AAV VECTOR PRODUCTION

Attorney Docket No.: 2578-5148US
Serial No.: 10/002,750
Filing Date: November 15, 2001
Title: COMPLEMENTING CELL LINES

Attorney Docket No.: 2578-5226US
Serial No.: 10/040,949
Filing Date: January 7, 2002
Title: INFECTION WITH CHIMAERIC ADENOVIRUSES OF CELLS
NEGATIVE FOR THE ADENOVIRUS SEROTYPE 5 COXSACKI
ADENOVIRUS RECEPTOR (CAR)

Attorney Docket No.: 2578-5233US
Serial No.: 10/042,770
Filing Date: January 9, 2002
Title: GENE THERAPY FOR ENHANCING AND/OR INDUCING
ANGIOGENESIS

Attorney Docket No.: 2578-5233.1US
Serial No.: 10/224,249
Filing Date: August 19, 2002
Title: GENE THERAPY FOR ENHANCING AND/OR INDUCING
ANGIOGENESIS

Attorney Docket No.: 2578-5592US
Serial No.: 10/305,435
Filing Date: November 25, 2002
Title: METHODS AND MEANS FOR ENHANCING SKIN
TRANSPLANTATION USING GENE DELIVERY VEHICLES
HAVING TROPISM FOR PRIMARY FIBROBLASTS, AS WELL AS
OTHER USES THEREOF (PRIMAIRE FIBROBLASTEN)

Attorney Docket No.: 2578-5832US
Serial No.: 10/381,088
Filing Date: 3/20/2003
Title: ADENOVIRAL VECTORS PROVIDED WITH A TROPISM FOR
DENDRITIC CELLS

Serial No. 10/010,645

Attorney Docket No.: 2578-5904US
Serial No.: 10/381,857
Filing Date: March 26, 2003
Title: ADENOVIRAL VECTORS FOR GENE DELIVERY IN SKELETAL
MUSCLE CELLS OR MYOBLASTS

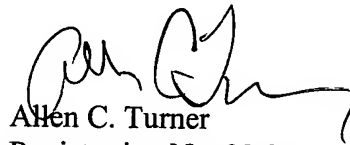
Attorney Docket No.: 2578-6077US
Serial No.: 10/644,256
Filing Date: August 20, 2003
Title: EFFICIENT PRODUCTION OF IgA IN RECOMBINANT
MAMMALIAN CELLS

Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits.

The fee pursuant to 37 C.F.R. § 1.17(p) is enclosed.

Respectfully submitted,



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Date: September 30, 2003
ACT/jml

Enclosures: Form PTO/SB/08A
Cited Documents
Check in the amount of \$180.00

Document in ProLaw

PTO/SB/08A (10-01)



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet <u>2</u> of <u>3</u>		Complete if Known	
		Application Number	10/010,645
		Filing Date	November 13, 2001
		First Named Inventor	Havenga et al.
		Group Art Unit	1645
		Examiner Name	B. Whiteman
		Attorney Docket Number	2578-5006 IJIS

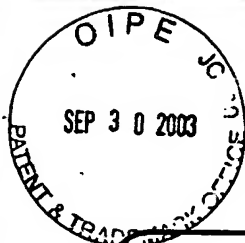
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		CONGET, P.A., et al., "Adenoviral-mediated gene transfer into ex vivo expanded human bone marrow mesenchymal progenitor cells," 28 EXPERIMENTAL HEMATOLOGY 382-390 (2000).	
		GOOSSENS, P.H., et al., "Infection Efficiency of Type 5 Adenoviral Vectors in Synovial Tissue Can Be Enhanced With a Type 16 Fiber," 44(3) ARTHRITIS & RHEUMATISM 570-577 (March 2001).	
		HAVENGA, M.J.E., et al., "Exploiting the Natural Diversity in Adenovirus Tropism for Therapy and Prevention of Disease," 76(9) JOURNAL OF VIROLOGY 4612-4620 (May 2002).	
		HAVENGA, M.J.E., et al., "Improved Adenovirus Vectors for Infection of Cardiovascular Tissue," 75(7) JOURNAL OF VIROLOGY 3335-3342 (Apr. 2001).	
		MARX, J.C., et al., "High-Efficiency Transduction and Long-Term Gene Expression with a Murine Stem Cell Retroviral Vector Encoding the Green Fluorescent Protein in Human Marrow Stromal Cells," 10 HUMAN GENE THERAPY 1163-1173 (May 1, 1999).	
		OLMSTED-DAVIS, E.A., et al., "Use of a Chimeric Adenovirus Vector Enhances BMP2 Production and Bone Formation," 13 HUMAN GENE THERAPY 133-1347 (July 20, 2002).	
		ROELVINK, P.W., et al., "Identification of a Conserved Receptor-Binding Site on the Fiber Proteins of CAR-Recognizing Adenoviridae," 286 SCIENCE 1568-1571 (Nov. 1999).	
		ROELVINK, P.W., et al., "The Coxsackievirus-Adenovirus Receptor Protein Can Function as a Cellular Attachment Protein for Adenovirus Serotypes from Subgroups A, C, D, E, and F," 72(10) JOURNAL OF VIROLOGY 7909-7915 (Oct. 1998).	
		TURGEMAN, G., et al., "Bone Stem Cell Mediated Gene Therapy and Tissue Engineering," 15(7) JOURNAL OF BONE AND MINERAL RESEARCH S196 (Sept. 2000), Abstract.	
		TURGEMAN, G., et al., "Engineered human mesenchymal stem cells: a novel platform for skeletal cell mediated gene therapy," 3 J. GENE MED. 240-251 (2001).	
		VIGGESWARAPU, M., et al., "Adenoviral Delivery of LIM Mineralization Protein-1 Induces New-Bone Formation in Vitro and in Vivo," 83-A(3) THE JOURNAL OF BONE & JOINT SURGERY 364-376 (March 2001).	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B(10-01)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3

Complete if Known

Application Number	«Patent Application No»
Filing Date	«Patent Filing Date: July 4, 1996»
First Named Inventor	«Inventor Short Form for Applicant»
Group Art Unit	«Patent Group Art Unit»
Examiner Name	«Patent Examiner»
Attorney Docket Number	«Matter Matter ID»

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		YOTNDA, P., et al., "Efficient infection of primitive hematopoietic stem cells by modified adenovirus," 8(12) GENE THERAPY 930-937 (June 2001).	
		Partial European Search Report, European Application No. 01202619, dated May 7, 2002 (4 pages).	
		International Search Report, International Application No. PCT/NL02/00443, dated July 24, 2003 (6 pages).	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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